

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TWINSTRAND BIOSCIENCES, INC. &
UNIVERSITY OF WASHINGTON,

Plaintiffs,

v.

C.A. No. 21-1126-GBW-SRF

GUARDANT HEALTH, INC.,

Defendant.

MEMORANDUM ORDER

Pending before the Court are Defendant Guardant Health, Inc.’s (“Guardant”) objections (D.I. 152) to the Magistrate Judge’s October 28, 2022 Report and Recommendation (“Report,” *see* D.I. 145), and Plaintiffs Twinstrand Biosciences, Inc.’s (“Twinstrand”) and University of Washington’s (“UW” and, collectively, “Plaintiffs”) response thereto (D.I. 160). For the following reasons, Guardant’s objections are overruled, and the Court will adopt the Magistrate Judge’s Report.

I. STANDARD OF REVIEW

In reviewing a Magistrate Judge’s Report and Recommendation, the Court must “make a de novo determination of those portions of the report or specified proposed findings or recommendations to which objection is made.” 28 U.S.C. § 636(b)(1)(C). The Court may “accept, reject, or modify, in whole or in part” the Magistrate Judge’s findings or recommendations. *Id.* As to those portions to which no objections have been made, the Court must “satisfy itself that there is no clear error on the face of the record in order to accept the recommendation.” FED. R. CIV. P. 72(b) Advisory Committee Notes; *see Henderson v. Carlson*, 812 F.2d 874, 878 (3d Cir.

1987) (explaining the district court’s responsibility “to afford some level of review” when no objections have been made).

II. LEGAL STANDARD

A. Motion to Dismiss

To state a claim on which relief can be granted, a complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief” Fed. R. Civ. P. 8(a)(2). Such a claim must plausibly suggest “facts sufficient to ‘draw the reasonable inference that the defendant is liable for the misconduct alleged.’” *Doe v. Princeton Univ.*, 30 F.4th 335, 342 (3d Cir. 2022) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). “A claim is facially plausible ‘when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.’” *Klotz v. Celentano Stadtmauer & Walentowicz LLP*, 991 F.3d 458, 462 (3d Cir. 2021) (quoting *Iqbal*, 556 U.S. at 678). However, the Court will “disregard legal conclusions and recitals of the elements of a cause of action supported by mere conclusory statements.” *Princeton Univ.*, 30 F.4th at 342 (citation omitted).

“‘The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.’” *Pinnavaia v. Celotex Asbestos Settlement Tr.*, 271 F. Supp. 3d 705, 708 (D. Del. 2017) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997)), *aff’d*, 2018 WL 11446482 (3d Cir. Apr. 6, 2018). “A motion to dismiss ‘may be granted only if, accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief.’” *McCrone v. Acme Markets*, 561 F. App’x 169, 172 (3d Cir. 2014) (quoting *Burlington Coat Factory*, 114 F.3d at 1420).

B. Motion to Strike

Pursuant to Federal Rule of Civil Procedure 12(f), a court “may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” “The court may act: (1) on its own; or (2) on motion made by a party either before responding to the pleading or, if a response is not allowed, within 21 days after being served with the pleading.” Fed. R. Civ. P. 12(f). Motions to strike are generally “disfavored.” *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 356 (D. Del. Mar. 30, 2009) (citing *Seidel v. Lee*, 954 F. Supp. 810, 812 (D. Del. Dec. 30, 1996)). “When ruling on a motion to strike, the [c]ourt must construe all facts in favor of the nonmoving party and deny the motion if the defense is sufficient under law.” *Symbol Techs.*, 609 F. Supp. 2d at 356 (quoting *Procter & Gamble Co. v. Nabisco Brands, Inc.*, 697 F. Supp. 1360, 1362 (D. Del. Oct. 21, 1988)) (internal quotations omitted). “[A] court should not grant a motion to strike a defense unless the insufficiency of the defense is ‘clearly apparent.’” *Cipollone v. Liggett Grp., Inc.*, 789 F.2d 181, 188 (3d Cir. 1986), *rev’d on other grounds*, 505 U.S. 504, 112 (1992) (citations omitted).

III. DISCUSSION¹

The Magistrate Judge’s Report recommended: (1) denying Plaintiffs’ Rule 12(b)(6) Motion to Dismiss Guardant’s Counterclaims V and VI to the extent those counterclaims are based on a failure to name the corrected inventors under 35 U.S.C. §§ 101 and 115; (2) granting Plaintiffs’ Rule 12(b)(6) Motion to Dismiss Guardant’s Counterclaims V to the extent it is based on 35 U.S.C. § 135(b); (3) granting Plaintiffs’ Rule 12(b)(6) Motion to Dismiss Guardant’s Counterclaims VII and VIII; (4) granting Plaintiffs’ Motion to Strike Guardant’s Twelfth Affirmative Defense; (5)

¹ The Court writes for the benefit of the parties and assumes their familiarity with this action.

denying Plaintiffs' Motion to Strike Guardant's Fourth and Eighth² Affirmative Defenses; and (6) denying Plaintiffs' Motion to Sever and Stay Guardant's Counterclaims I to IV without prejudice. *See generally* D.I. 145.

As discussed in greater detail below, with respect to those recommendations where neither party has filed an objection, the Court is satisfied that "there is no clear error on the face of the record," *see* FED. R. CIV. P. 72(b) Advisory Committee Notes, and will therefore adopt the Magistrate Judge's recommendations. Further, with respect to Guardant's objections to the Magistrate Judge's Report, the Court, having reviewed the record *de novo*, agrees that Guardant has failed to adequately plead facts sufficient to state a claim for inequitable conduct (Counterclaims VII and VIII) and invalidity pursuant to 35 U.S.C. § 135 (Counterclaim V and Twelfth Affirmative Defense). As such, the Magistrate Judge's Report is ADOPTED, and Plaintiffs' Motion to Dismiss Guardant's Counterclaims V—to the extent it is based on 35 U.S.C. § 135(b)—, VII, VIII, and Plaintiffs' Motion to Strike Guardant's Twelfth Affirmative Defense are GRANTED.

A. No Objections to the Magistrate Judge's Report

Neither party filed an objection to the Magistrate Judge's Report (1) denying Plaintiffs' Rule 12(b)(6) Motion to Dismiss Guardant's Counterclaims V and VI to the extent those counterclaims are based on a failure to name the corrected inventors under 35 U.S.C. §§ 101 and

² The Magistrate Judge's Report recommends "that the court deny Plaintiffs' motion to strike Guardant's Eight Affirmative Defense for unclean hands" because Plaintiff's argument was not squarely addressed and, thus, was deemed waived. *See* D.I. 145 at 20. However, in the "Conclusion" section of the Magistrate Judge's Report, *see id.* at Section III, the Magistrate Judge "recommend[s] that the court GRANT Plaintiffs' motion to strike Guardant's Eighth . . . Affirmative Defense[]." *Id.* at 24. The Court believes that this conclusion-sentence of the Magistrate Judge's Report was a simple scrivener's error and, therefore, understands the Magistrate Judge as recommending the Court deny Plaintiffs' Motion to Strike Guardant's Eighth Affirmative Defense.

115, (2) denying Plaintiffs' Motion to Strike Guardant's Fourth Affirmative Defense, or (3) denying Plaintiffs' Motion to Sever and Stay Guardant's Counterclaims I to IV without prejudice. Thus, to accept these recommendations from the Magistrate Judge's Report, the Court need only satisfy itself that there "is no clear error on the face of the record." FED. R. CIV. P. 72(b) Advisory Committee Notes.

Accordingly, the Court agrees with the Report's conclusions. At the pleading stage, the sufficiency of a cause of action for patent invalidity pursuant to 35 U.S.C. §§ 101 and 115 is governed by Rule 8 of the Federal Rules of Civil Procedure, as opposed to the heightened pleading standard of Rule 9(b). *See Belcher Pharms., LLC v. Hospira, Inc.*, No. 17-775-LPS, 2019 WL 2503159, at *1 (D. Del. June 5, 2019); *see also* D.I. 145 at 16. As the Magistrate Judge correctly concludes, Guardant's Counterclaims V and VI sufficiently plead allegations that give rise to a plausible inference that the claimed inventions of the '699 and '951 patents were not made by the named inventors and, instead, were copied from Guardant's '822 patent and '427 application. D.I. 145 at 16-17; *see also* D.I. 30 at ¶¶ 124, 141-42, 145-46, 233-345, 242. Thus, the Court will adopt the Magistrate Judge's recommendation denying Plaintiffs' Motion to Dismiss Counterclaims V and VI for unpatentability under 35 U.S.C. §§ 101 and 115. Additionally, the Court concludes that, because portions of Counterclaims V and VI remain viable, Plaintiffs' request to dismiss UW as a counterclaim defendant is also denied. *See* D.I. 145 at 17.

Further, because Guardant's Fourth Affirmative Defense is coextensive with Guardant's Counterclaims V and VI, the Court adopts the Magistrate Judge's recommendation denying Plaintiffs' Motion to Strike Guardant's Fourth Affirmative Defense. *Id.* at 20. Moreover, the Court agrees with the Magistrate Judge's conclusions that, on balance, the factors weigh against staying proceedings with respect to Guardant's Counterclaims I to IV, *see Am. Axle & Mfg., Inc.*

v. Neapco Holdings LLC, C.A. No. 15-1168-LPS, 2021 WL 616992, at *2 (D. Del. Feb. 17, 2021) (citing *Ethicon LLC v. Intuitive Surgical, Inc.*, C.A. No. 17-871-LPS, 2019 WL 1276029, at *1 (D. Del. Mar. 20, 2019))), and that Plaintiffs’ Motion to Sever Counterclaims I to IV rise and fall with the outcome of the Motion to Stay. *See* D.I. 145 at 20-24. Thus, the Court adopts the Magistrate Judge’s Report recommending that the Court deny Plaintiffs’ Motion to Sever and Stay Guardant’s Counterclaims I to IV without prejudice.

Finally, as explained above, *see supra* pg. 4 at n.2, the Court understands the Magistrate Judge’s Report as recommending the Court deny Plaintiffs’ Motion to Strike Guardant’s Eighth Affirmative Defense for unclean hands due to Plaintiffs’ waiver. D.I. 145 at 20. Although Guardant objects, Guardant’s objection is premised on the Report scrivener’s error recommending the Court grant Plaintiffs’ Motion to Strike. As such, Guardant’s objection is moot. Thus, the Court need only satisfy itself that there “is no clear error on the face of the record.” FED. R. CIV. P. 72(b) Advisory Committee Notes. The Court agrees that Plaintiffs waived this argument by failing to squarely argue it in the body of their motion. *See Samsung Elecs. Co. v. Netlist, Inc.*, No. 21-1453-RGA, 2022 WL 3027312, at *5 (D. Del. Aug. 1, 2022) (finding that, because an argument seeking to strike an affirmative defense of unclean hands was lodged in a footnote, the argument was waived). Consequently, the Court adopts the Magistrate Judge’s Report recommending that Plaintiffs’ Motion to Strike Guardant’s Eighth Affirmative Defense for unclean hands be denied.

B. Guardant’s Objections to the Magistrate Judge’s Report

Guardant timely objected to the Magistrate Judge’s Report recommending the Court grant Plaintiffs’ Rule 12(b)(6) Motion to Dismiss Guardant’s Counterclaims VII and VIII, grant Plaintiffs’ Rule 12(b)(6) Motion to Dismiss Guardant’s Counterclaims V to the extent it is based

on 35 U.S.C. § 135(b), and grant Plaintiffs’ Motion to Strike Guardant’s Twelfth Affirmative Defense. *See* D.I. 152. The Court addresses each objection in turn.

i. Guardant’s Inequitable Counterclaims (Counterclaims VII and VIII)

“Inequitable conduct is a defense to patent infringement that, if proven, renders the asserted patent unenforceable. ‘To prevail on an inequitable conduct defense, a defendant must establish both [1] the materiality of the withheld reference and [2] the applicant’s intent to deceive the PTO.’” *Belcher Pharms., LLC v. Hospira, Inc.*, 11 F.4th 1345, 1352 (Fed. Cir. 2021) (citations omitted); *see Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1334 (Fed. Cir. 2012) (also requiring intent and but-for materiality). “Whether inequitable conduct has been pleaded with particularity under Rule 9(b) is a question governed by Federal Circuit law.” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1318 (Fed. Cir. 2009). “A pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy Rule 9(b).” *Id.* at 1326–27.

[T]o plead the “circumstances” of inequitable conduct with the requisite “particularity” under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO. Moreover, although “knowledge” and “intent” may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.

Id. at 1328–29; *see Analog Devices, Inc. v. Xilinx, Inc.*, 2021 WL 466859, at *1 (D. Del. Feb. 9, 2021) (quoting *Exergen*, 575 F.3d at 1328–29). “A reasonable inference is one that is plausible and that flows logically from the facts alleged” *Exergen*, 575 F.3d at 1329 n.5.

Guardant argues that the Magistrate Judge’s finding that Guardant’s Counterclaims VII and VIII fail to sufficiently allege the materiality of Plaintiffs’ omissions to the PTO is clearly

erroneous because Guardant adequately explains both “why” the omitted information is material and “how” such information would have affected the patentability of the ’699 and ’951 patents. D.I. 152 at 1-2. Specifically, Guardant contends that its “counterclaims adequately allege both ‘per se’ and ‘but-for’ materiality, either of which is sufficient to state a claim for inequitable conduct.”³ D.I. 152 at 2.

According to *Therasense*, which the Magistrate Judge’s Report cites, but-for materiality must be pled to satisfy the materiality prong of inequitable conduct, except in cases which plead *per se* materiality based on “affirmative acts of egregious misconduct,” such as the submission of a false affidavit or declaration to the USPTO. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292-93 (Fed. Cir. 2011); D.I. 145 at 9-10. Guardant’s inequitable conduct counterclaims are undisputedly based on Plaintiffs’ alleged failure to notify the PTO, i.e., an omission, of claim copying in the applications that led to the ’699 and ’951 patents. *See* D.I. 30 at ¶¶ 257, 282. Thus, Guardant has failed to sufficiently plead **affirmative** acts of egregious misconduct to plead *per se* materiality. *See Therasense*, 649 F.3d at 1292. Guardant’s objections fail to present any case law that holds, or otherwise suggests, that an omission by a patentee of claim copying information, pursuant to MPEP § 2001.06(d), is an affirmative act of egregious

³ Plaintiffs contend that Guardant waived its *per se* materiality argument because Guardant “did not raise any *per se* materiality argument in its Opposition Brief to Plaintiffs’ Motion to Dismiss.” D.I. 160 at 2 (citing *Masimo Corp. v. Philips Elec. N. Am. Corp.*, 62 F. Supp. 3d 368, 377 (D. Del. 2014) (“[W]ith limited (if any) exception, parties objecting to a Magistrate Judge’s report or order are required to adhere to the arguments, evidence, and issues they presented first to the Magistrate Judge.”)). While Guardant never uses the phrase “*per se*” in its Opposition Brief, the Court finds that Guardant did sufficiently address the **substance** of its *per se* materiality argument to preserve this theory at this stage. *See* D.I. 43 at 12.

misconduct.⁴ Therefore, having reviewed the record *de novo*, the Court agrees with the Magistrate Judge’s conclusion that, to the extent Guardant’s Counterclaims VII and VIII are based on *per se* materiality, Guardant has failed to plead sufficient facts to survive a motion to dismiss. D.I. 145 at 10.

Turning to “but-for” materiality, Guardant contends that its allegations that “the recited claim copying was expressly time-barred under the one-year time limits in 35 U.S.C. § 135(b),” and that “the ’699 and ’951 patents ‘would not have issued if [the inventors and counsel] had notified the PTO of the copied claims,” is sufficient to plead but-for materiality. D.I. 152 at 4-5; D.I. 30 at ¶¶ 246-50, 272-75. But notably absent from Guardant’s pleading are allegations that the alleged violation of 35 U.S.C. § 135(b) would have caused the examiner to reject the purported copied claims or how the alleged violation of 35 U.S.C. § 135(b) would have adversely impacted the issuance of the ’699 and ’951 patents. While Guardant does allege that “[o]n information and belief, the [’699 and ’951 patents] would not have issued if Jesse Salk, Lawrence Loeb, Michael Schmitt, and Lara J. Dueppen had notified the PTO of the copied claims,” *see* D.I. 30 at ¶¶ 263, 288, this amounts to nothing more than a bare recitation of the materiality element, which cannot meet the heightened pleading standard of Rule 9(b). *Analog Devices*, 2021 WL 466859, at *3; *Allergan USA, Inc. v. Prolenium US Inc.*, 2019 WL 7298569, at *3 (D. Del. Dec. 9, 2019) (“The

⁴ Guardant’s citations to *Mosaic Brands* and *Cutsforth* are unpersuasive. D.I. 152 at 4. *Mosaic Brands* plainly did not analyze the pleading requirement of *per se* materiality, i.e., “affirmative acts of egregious misconduct,” and is, therefore, inapplicable. *See Mosaic Brands, Inc. v. Ridge Wallet LLC*, 2021 WL 4533271, at *4-5 (C.D. Cal. July 1, 2021). Similarly, *Cutsforth* did not address the *per se* materiality pleading requirement and, notably, has been criticized for skipping the critical step of “determining whether the [omitted materials] meet the ‘but-for materiality’ test.” *See, e.g., Cutsforth, Inc. v. LEMM Liquidating Co., LLC*, 2013 WL 2455979, at *7 (D. Minn. June 6, 2013); *Flypsi, Inc. v. Dialpad, Inc.*, 2022 WL 3593132, *5 (W.D. Tex. Aug. 22, 2022) (“This Court believes that Cutsforth skipped a critical analytical step—determining whether the [omitted materials] meet the ‘but-for materiality’ test.”).

use of boiler plate and conclusory allegations will not suffice.”). Similarly, Guardant’s argument that but-for materiality is sufficiently pled because it alleges “the disclosure of claim copying would have triggered an interference under 35 U.S.C. § 135(a),” together with its allegation that ’699 and ’951 patents “would not have issued if [the inventors and counsel] had notified the PTO of the copied claims,” fares no better. *See* D.I. 152 at 5; D.I. 30 at ¶¶ 262-63, 287-88. Again, absent from Guardant’s pleading are allegations that Plaintiffs were likely to lose a potential interference proceeding, or that the claims of the ’699 and ’951 patents would have been adversely impacted by the result of an interference. What Guardant does allege are simply boilerplate recitations of the materiality element, which simply cannot support a claim for inequitable conduct. *See Analog Devices*, 2021 WL 466859, at *3. As such, the Court, reviewing the record *de novo* and drawing all reasonable inferences in favor of Guardant, agrees with the Magistrate Judge’s Report concluding that Guardant has failed to plead sufficient facts to establish the materiality element of the inequitable conduct cause of action. D.I. 145 at 11-12.

Finally, the Magistrate Judge’s Report concluded that Guardant’s Counterclaims VII and VIII fail to allege facts sufficient to “sustain a reasonable inference that the named inventors and prosecution counsel made a deliberate decision to deceive the USPTO during the prosecution of the ’699 and ’951 patents by concealing their claim copying activities.” D.I. 145 at 13. Guardant objects, arguing that, based on its factual allegations, “deceptive intent is the only reasonable inference to draw.” D.I. 152 at 7. Reviewing the pleadings *de novo*, Guardant alleges that, because the named inventors and prosecution counsel engaged in a “practice of copying claims into their own applications without disclosing that the claims are copied,” one could reasonably infer that the inventors engaged in a purposeful effort to copy claims without disclosing such activity to the PTO. D.I. 30 at ¶¶ 265, 290. But, as the Magistrate Judge correctly notes, the inference Guardant

attempts to draw is belied by its own allegation that the allegedly copied references were disclosed to the PTO in an information disclosure statement (“IDS”). *Id.* at ¶ 252 (conceding that the applicants “cited the ’822 Patent in [the application that led to the ’699 patent’s] June 18, 2019 Information Disclosure Statement”); *id.* at ¶¶ 265, 290 (conceding that four of the five alleged claim copying instances were disclosed to the PTO in applicants’ IDS). Even taking Guardant’s allegations as true, the Court cannot reasonably infer that Plaintiffs intended to conceal their copying activities when Plaintiffs disclosed those copied references in an IDS. *See, e.g., Allergan*, 2019 WL 7298569, at *8 (disclosing a prior art reference in an IDS indicates a lack of specific intent to deceive the PTO); *Pixion, Inc. v. Citrix Sys., Inc.*, 2012 WL 762005, at *6 (N.D. Cal. Mar. 8, 2012) (same); *Exergen*, 575 F.3d at 1329 n.5 (“A reasonable inference is one that is plausible and that flows logically from the facts alleged.”). While Guardant attempts to circumvent its own allegations by arguing that one could still reasonably infer a specific intent to deceive because Plaintiffs’ “IDS’s did not say anything about why the references might be relevant,” *see* D.I. 152 at 8, Guardant overlooks that an IDS does not require an explanation of a references’ relevance.⁵ *See* 37 C.F.R. § 1.98. Moreover, Guardant’s Counterclaim VIII fails to assert sufficient facts to reasonably infer that either the prosecution attorney or the inventors of the ’951 patent were aware of the specific claims allegedly copied from Guardant’s ’427 application. D.I. 30 at ¶¶ 277, 275, 282. What Guardant does allege is that the inventors were aware of Guardant’s ’427 application because they cited it in their own application filed two years prior to prosecuting the ’951 patent, *see id.*, but the Court cannot reasonably infer that “an individual, who generally knew that a

⁵ Guardant’s objection also advances the argument that the applicants of the ’699 patent “disclosed hundreds of references during prosecution,” which “gives rise to a reasonable inference that the inventors and their counsel intended to bury this reference among the others.” D.I. 152 at 8-9. But Guardant never presented this argument in its briefing to the Magistrate Judge. Thus, this argument is waived. *See Masimo Corp.*, 62 F. Supp. 3d at 377.

reference existed, also knew of the specific material information contained in that reference.”

Exergen, 575 F.3d at 1330.

Therefore, having reviewed Guardant’s pleadings *de novo*, the Court agrees with the Magistrate Judge’s conclusion that “Guardant has failed to adequately plead the materiality and intent prongs of their counterclaims for inequitable conduct.” D.I. 145 at 16. As such, the Court adopts this portion of the Magistrate Judge’s Report and grants Plaintiffs’ Motion to Dismiss Guardant’s Counterclaims VII and VIII without prejudice.

ii. Guardant’s Counterclaim and Affirmative Defense Based on 35 U.S.C. § 135(b) (Counterclaim V and Twelfth Affirmative Defense)

Both Guardant’s Counterclaim V⁶ and Twelfth Affirmative Defense seek to invalidate the ’699 patent for failure to comply with one or more conditions of patentability prescribed in 35 U.S.C. § 135. D.I. 30 at 21; *see also id.* at ¶¶ 226-35. The parties agree that the pre-America Invents Act (“AIA”) version of 35 U.S.C. § 135 applies to the analysis of whether the ’699 patent is invalid. D.I. 39 at 17-18; D.I. 43 at 14. Pre-AIA § 135(b)(1) provides that “[a] claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.” 35 U.S.C. § 135(b) (pre-AIA). Guardant objects to the Magistrate Judge’s recommendation granting Plaintiffs’ Motion to Dismiss Counterclaim V and Motion to Strike the Twelfth Affirmative Defense, arguing that the Magistrate Judge erred in concluding that

⁶ Guardant’s Counterclaim V additionally seeks a declaration of unpatentability of the ’699 patent for failure to comply 35 U.S.C. §§ 101, 115. *See* D.I. 30 at ¶¶ 226-35. For purposes of clarity, this section of the Court’s Memorandum Order only addresses the sufficiency of Guardant’s Counterclaim V and Twelfth Affirmative Defense with respect to 35 U.S.C. § 135. As discussed above, *see supra* Section III.A, the Court has already adopted the Magistrate Judge’s recommendation denying Plaintiffs’ Motion to Dismiss Counterclaims V and VI for unpatentability under 35 U.S.C. §§ 101 and 115.

§ 135(b)(1) does not provide a cause of action for invalidity. D.I. 152 at 10. However, Guardant fails to cite any authority holding that § 135(b) can serve as a substantive basis for invalidity. That makes sense, considering “[b]oth the plain language of that provision and the relevant legislative history make clear that [§ 135(b)] was intended to be a statute of repose, limiting the time during which an interference may be declared ‘so that the patentee might be more secure in his property right.’” *Berman v. Housey*, 291 F.3d 1345, 1351 (Fed. Cir. 2002) (quoting *Corbett v. Chisholm*, 568 F.2d 759, 765 (C.C.P.A. 1977)); *see also* H.R. Rep. No. 970, at 1 (1939) (“The purpose of this bill is to curtail the time within which an interference with an issued patent may be instituted.”). Accordingly, the Court agrees with the Magistrate Judge’s conclusion that Guardant’s Counterclaim V, to the extent it is based on § 135(b), and its Twelfth Affirmative Defense must be dismissed because § 135(b) does not serve as a standalone basis for invalidity. D.I. 145 at 18-20.

IV. CONCLUSION

For the foregoing reasons, Guardant’s objections (D.I. 152) are OVERRULED. Based on the Court’s *de novo* review of the record, Guardant has failed to state a claim for inequitable conduct (Guardant’s Counterclaims VII and VIII) and has failed to establish that 35 U.S.C. § 135(b) (pre-AIA) can serve as a standalone basis for invalidity (Guardant’s Counterclaim V, to the extent it is based on § 135(b), and the Twelfth Affirmative Defense). 28 U.S.C. § 636(b)(1)(C). With respect to portions of the Magistrate Judge’s Report that were not objected to, the Court ADOPTS the Magistrate Judge’s Report.

* * *

WHEREFORE, at Wilmington this 9th day of February, 2023, **IT IS HEREBY ORDERED** that:

1. Defendant Guardant's Objections (D.I. 152) to the Magistrate Judge's Report are **OVERRULED**;
2. The Magistrate Judge's Report (D.I. 145) is **ADOPTED**;
3. Plaintiffs' Partial Motion to Dismiss and Motion to Strike (D.I. 38) are **GRANTED-IN-PART** and **DENIED-IN-PART**;
 - a. Guardant's Counterclaims VII and VIII are dismissed without prejudice;
 - b. Guardant's Counterclaim V, to the extent it is based on § 135(b) (pre-AIA), is dismissed with prejudice;
 - c. Guardant's Twelfth Affirmative Defense is stricken.
4. Plaintiffs' request seeking dismissal of University of Washington as a counterclaim-defendant is **DENIED**; and
5. Plaintiffs' Motion to Sever and Stay Counterclaims I to IV (D.I. 75) is **DENIED** without prejudice.



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE